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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,129	06/24/2003	David J. Schuessler	33915-03420	9875

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MILBANK, TWEED, HADLEY & MCCLOY LLP  
1 CHASE MANHATTAN PLAZA  
NEW YORK, NY 10005-1413

EXAMINER

MIGGINS, MICHAEL C

ART UNIT PAPER NUMBER

1772

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/603,129

Applicant(s)

SCHUESSLER, DAVID J.

Examiner

Michael C. Miggins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/27/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

#### **REJECTIONS WITHDRAWN**

1. All of the 35 USC 102(b) and 103(a) rejections set forth in the non-final rejection of 6/24/05, pages 4-7, paragraphs 8-13 are withdrawn.

#### **REJECTIONS REPEATED**

2. There are no rejections repeated.

#### **NEW REJECTIONS**

##### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 23-25, 28-31, 35-36, 39-42 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al. (US 4960425).

Claim 23 contains the method limitation “rotationally molded” which is a method limitation in a product and has been given little patentable weight since the method limitation does not structurally further limit the product (MPEP 2113). Claims 39-42 contain method limitations as to how the silicone is cured (acetoxo-cured, platinum catalyzed, tin catalyzed) which have been given little patentable weight because the limitations do structurally further limit the product claim (MPEP 2113).

Yan discloses a medical article, breast implant (abstract), comprising a shell defining an interior cavity, said shell being formed of at least one layer of a non-olefin polymer material, wherein said shell is textured (column 8, lines 5-33), seamless (column 7, lines 5-15), filled with a silicone gel, a saline solution, or a foam (column 2, lines 32-47), wherein the polymer material is silicone, polyurethane, or elastomer (column 8, lines 5-33) (applies to instant claims 23-25, 28-31, 35-36, 39-42 and 45).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 32-34, 37-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US 4960425).

Yan does not specifically disclose a removable liner. However, it would have been obvious to have provided a removable liner in order to protect the prosthesis during transport or storage (applies to instant claims 32-34).

Yan does not specifically disclose that the medical article is an elastomeric balloon or a catheter balloon. However, Yan does disclose an expandible prosthesis (column 2, lines 32-47) and thus the prosthesis of Yan could easily be formed into a balloon type prosthesis for the purpose of a prosthesis which enhances anchoring of the prosthesis in the body (applies to instant claims 32-34, 37-38).

7. Claims 27 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US 4960425) in view of XP-002334285 (from ROTATION MAGAZINE, provided by applicant in the IDS of 9/27/05).

Yan fails to specifically disclose the thickness range recited in claim 27. However, XP-002334285 discloses that the thickness of a hollow prosthesis made from silicone or polyurethane polymers is variable (see Introduction and Thickness Control sections). Therefore it would have been obvious to one of ordinary skill in the art to vary the thickness of the prosthesis in order to reduce costs and/or improve the aesthetic appearance of the prosthesis (applies to instant claim 27).

Yan fails to disclose that the shell of the prosthesis is formed from a solvent-based polymer or a polymer which emits gaseous by-products during curing. However, XP-002334285 discloses that the shell of the prosthesis is formed from a solvent-based polymer or a polymer which emits gaseous by-products during curing (see Introduction and Bubbles In Polymer Melts/Solutions sections) in order to improve the aesthetic appearance of the prosthesis (applies to instant claims 43-44).

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (US 4960425) in view of Prah (US 4426742).

Yan fails to disclose wherein the shell of the prosthesis is patchless. Prah discloses a shell of a prosthesis which is patchless (column 4, lines 41-64) (applies to

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instant claim 26) in order to provide a stronger prosthesis less likely to leak and/or ease of construction.

### **ANSWERS TO APPLICANT'S ARGUMENTS**

9. Applicant's arguments filed 8/9/05 have been carefully considered but are moot in view of the new grounds for rejection set forth above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Miggins

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Primary Examiner

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A handwritten signature in black ink, appearing to read "Michael C. Tyack", with a stylized flourish at the end.

MCM

October 31, 2005